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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,464	06/22/2001	Gerard H. Llanos	CRD-0929	8413

27777 7590 08/23/2004

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EXAMINER

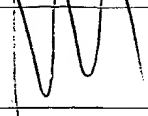
ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/887,464	Applicant(s) LLANOS ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16 and 17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>31 march 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated June 15, 2004. Claims 1-8, 16 and 17 are pending.

Response to Arguments

1. Applicant's arguments filed June 15, 2004 have been fully considered but they are not persuasive.

Applicant argues, "Chudzik fails to disclose a water-soluble powder affixed to the polymeric coating comprising a therapeutic dosage of an agent for treating certain reactions." However, as stated with in the previous office action dated March 17, 2004, although Chudzik et al. do not explicitly recite a water soluble powder it is within the scope of that discussed in section [0080] and would be obvious to one with ordinary skill in the art to have the lubricant be a water soluble powder according to the method of coating and well within the scope of the invention. Section [0080] recites:

[0080] If desired, for instance, such **an additional coating can be applied on top of a medicament absorbing layer**, either before and/or after medicament has been absorbed into the matrix. It is preferable to add the additional layer before medicament has been absorbed. For instance, a solution of the same or of a different copolymer can be prepared and the coated device dipped, **sprayed** or otherwise contacted with the solution and illuminated as described previously. The coated device can then be contacted with, e.g., soaked in, the medicament solution as described previously. Medicament will pass through the top coat and be absorbed by the underlying matrix. When placed in the body, the medicament will be released as described herein. Using such a method, a coating with **enhanced lubricity**, hemocompatibility, or other desired property ca be incorporated into the medical device surface,

thus forming a device coating that provides multiple desired properties.

This recitation clearly demonstrates that additional layers for lubricity can be applied. Powder is defined as a substance consisting of ground, pulverized, or otherwise finely dispersed solid particles according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Therefore, although the term powder has not been explicitly recited a coating that would be sprayed on can broadly be considered a powder for the process of spraying requires dispersion of fine particles. Further, this powder can be used to enhance lubricity where reducing tackiness is within the scope of lubricity. Moreover, applicant specification does not demonstrate the criticality of powder. Page 26 recites, "For other polymers, however powders *may* be utilized." Therefore, applicant has failed to define over the prior art of record. The rejection is reiterated below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. in US 2002/0041899.

Regarding claim 1, Chudzik et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as recited in

section [0002]; a layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or implantation thereof, as recited in section [0022]; and a second layer including a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the second layer including a lubricious material being affixed to the at least one of the medical device or a delivery system for the medical device, as recited in section [0080].

However, Chudzik et al. do not explicitly recite a second layer that has a water-soluble powder for preventing separation. On the other hand, a water soluble powder is within the scope of that discussed in section [0080] and it would be obvious to one with ordinary skill in the art to have the lubricant be a water soluble powder according to the method of coating and well within the scope of the invention. Further, the specification does not demonstrate the criticality of a "powder" not provide any examples of what the powder is comprised.

Regarding claim 2, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, a medical device that is an intraluminal medical device, as recited in sections [0065]-[0071].

Regarding claim 3, Chudzik et al., as modified, disclose that as applied to claim 2, as well as, an intraluminal device that is a stent, as recited in sections [0065]-[0071].

Regarding claim 4, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, the at least one agent that is an anti-proliferative, as recited in sections [0054]-[0063].

Regarding claim 5, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, the at least one agent that is an anti-inflammatory, as recited in sections [0054]-[0063].

Regarding claim 6, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, the at least one agent that is an anti-coagulant, as recited in section [0054]-[0063].

Regarding claim 7, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, the at least one agent that is an immunosuppressant, as recited in sections [0054]-[0063].

Regarding claim 8, Chudzik et al., as modified, disclose that as applied to claim 1, as well as, the at least one agent that is a non-viral gene introducer, as recited in sections [0054]-[0063].

Regarding claim 16, Chudzik et al., as modified, disclose that as applied to claim 15, as well as, a water soluble powder that is an anti-oxidant, as recited in sections [0054]-[0063].

Regarding claim 17, Chudzik et al., as modified, disclose that as applied to claim 15, as well as, a water-soluble powder that has an anti-coagulant, as recited in sections [0054]-[0063].

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

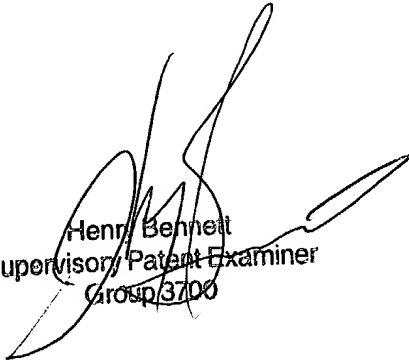
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Henry A. Bennett
Supervisory Patent Examiner
Group 3700